



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/887,505	07/02/97	KILKUSKIE	R HYZ-040CIP

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BOSTON MA 02109

HM31/1221

EXAMINER

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/21/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/887,505

Applicant(s)
Kilkuskie et al.

Examiner
Kenneth R. Horlick

Group Art Unit
1634



☒ Responsive to communication(s) filed on Oct 5, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-41 is/are pending in the application.

Of the above, claim(s) 35-41 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-21, 25, and 27-33 is/are rejected.

☒ Claim(s) 22-24, 26, and 34 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-31 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the methods, therapeutic compositions, and kits of the non-elected claims require as a limitation the oligonucleotides recited in the elected claims and, as such, are an integral part of these claims. This is not found persuasive because, as pointed out in the restriction requirement, the oligonucleotides of the elected group can be used in the materially different methods of groups II or III.

The requirement is still deemed proper and is therefore made FINAL. However, upon further consideration, the requirement is modified such that the pharmaceutical compositions of claims 32-34 are included with the elected Group I.

2. Claims 35-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 9. In the response, cancellation of claims 32-41 was intended; however these claims were not cancelled because the response did not include a formal request for cancellation. In light of the above modified restriction requirement, it is suggested that claims 35-41 be canceled.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Objections

4. Claim 7 is objected to because of the following informalities: There is no SEQ ID number given for one of the sequences listed. Appropriate correction is required.

5. Claim 34 is objected to under 37 CFR 1.75© as being in improper form because it is a multiple dependent claim, but does not refer to claims 32 and 1 or 2 in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

6. Claims 1, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 25, 27, 28, 29, 30, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are confusing because it cannot be determined what oligonucleotides are encompassed in the claims. Specifically, it is unclear whether the claimed oligonucleotides require only one sequence from either of the two recited groups of SEQ ID Nos, or require a sequence from both recited groups. Clarification is required.

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Claim Rejections - 35 USC § 102

7 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Kamada et al. (EP 0469342 A2).

Claim 1 is drawn to a synthetic oligonucleotide complementary to a portion of the 5' untranslated region of Hepatitis C virus having SEQ ID NO 2. Kamada et al. disclose SEQ ID NO: 15 used as a primer to detect Hepatitis C virus. SEQ ID NO: 15 is exactly the same as SEQ ID NO: 2 in the instant application (see pg. 25, SEQ ID NO: 15.)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2-6, 8-20, 25, 27, 28, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan, et al. (US Patent 5,424,413) in view of Maertens et al. (US Patent 5,846, 704).

These claims are drawn to an oligonucleotide comprising a sequence complementary to at least two non-contiguous regions of an HCV mRNA or genomic RNA.

Hogan discloses a nucleic acid hybridization probe having at least one nucleic acid strand which has at least two separate target specific regions that hybridize to a target nucleic acid sequence. (See Abstract, Drawing 4A). This patent also discloses the use of modified oligonucleotides, as well as therapeutic applications for oligonucleotides.

This patent does not disclose an HCV messenger or genomic RNA.

Maertens et al. disclose as their invention probes targeting sequences from the 5' untranslated region of HCV. (See Abstract.)

One of ordinary skill in the art would have been motivated to target the probe of Hogan et al to an HCV messenger or genomic RNA because Maertens et al disclosed the importance of detecting HCV nucleic acids. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

9. Claims 7 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan, et al. (US Patent 5,424,413) in view of Maertens et al. (US Patent 5,846, 704), and further in view of Seki et al.

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These claims are drawn to an oligonucleotide as described above, further comprising the specific recited sequences, including SEQ ID NO:47 and 160.

The teachings of Hogan et al and Maertens et al are discussed above.

These references do not disclose the specific nucleic acid sequences of the claims.

Seki et al disclose an oligonucleotide (SEQ ID NO:6) identical to instant SEQ ID NO:47.

Seki et al also disclose an oligonucleotide (SEQ ID NO:229) nearly identical to instant SEQ ID NO:160.

One of ordinary skill in the art would have been motivated to use probes containing the sequences of the cited references, or obvious variations thereof, in the method as discussed above because these would have clearly been useful in detecting HCV nucleic acids. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

10. Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan, et al. (US Patent 5,424,413) in view of Maertens et al. (US Patent 5,846, 704), and further in view of et al. Cha et al.

These claims are drawn to an oligonucleotide as described above, further comprising the specific recited sequences, including SEQ ID NO:122 and 117.

The teachings of Hogan et al and Maertens et al are discussed above.

These references do not disclose the specific nucleic acid sequences of the claims.

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Cha et al disclose an oligonucleotide (SEQ ID NO:15) nearly identical to instant SEQ ID NO:122. Seki et al also disclose an oligonucleotide (SEQ ID NO:39) nearly identical to instant SEQ ID NO:117.

One of ordinary skill in the art would have been motivated to use probes containing the sequences of the cited references, or obvious variations thereof, in the method as discussed above because these would have clearly been useful in detecting HCV nucleic acids. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

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Janell Taylor *jt*

12/21/98

KENNETH R. HORLICK
PRIMARY EXAMINER

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Kenneth R. Horlick, Ph.D.